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FOOD SAFETY

New Initiatives Would Fundamentally Alter the Existing System





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**Resources, Community, and
Economic Development Division**

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The Honorable Pat Roberts
Chairman
The Honorable E (Kika) de la Garza
Ranking Minority Member
Committee on Agriculture
House of Representatives

The Honorable Steve Gunderson
Chairman, Subcommittee on Livestock,
Dairy, and Poultry
Committee on Agriculture
House of Representatives

In response to continuing outbreaks of food poisoning, the Congress and federal agencies are considering new approaches to ensuring food safety. To assist the Congress with this effort, you asked us to provide you with information on the federal food safety system, particularly the current responsibilities, budgets, staffing, and workloads of the federal agencies involved and the changes in these areas since 1989.¹ You also asked us to provide you with information on the recent federal initiatives to improve the safety of meat, poultry, and seafood products.

Results in Brief

The federal structure and approach for ensuring food safety have changed little since 1989, but proposed initiatives would fundamentally alter this system. As in 1989, the responsibility for food safety is shared among multiple agencies; the Food and Drug Administration (FDA), in the Department of Health and Human Services, and the Food Safety and Inspection Service (FSIS), in the U.S. Department of Agriculture (USDA), continue to have principal regulatory authority. FDA is responsible for the safety of all foods, except for meat, poultry, and processed egg products, which are FSIS' responsibility. Another 10 agencies have responsibilities related to food safety, such as grading the quality of grains and conducting research. These 12 agencies carry out their duties much as they have always done, relying primarily on physical inspections of plants and food products. While the overall structure of and approach taken by the federal food safety system are essentially the same, new congressional directives and the growth in food production have led to an expansion in FDA's, FSIS',

¹We discussed the structure of the federal food safety system as of 1989 in our two-volume report entitled Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A and 19B, Dec. 21, 1990).

and the other agencies' workloads. From fiscal year 1989 through fiscal year 1994, the 12 agencies' budgets for food safety grew from \$851 million to nearly \$1.2 billion, or about \$170 million in constant 1989 dollars. While responsibilities, budgets, and workloads increased, staffing levels remained at about 17,000.

FDA and FSIS have proposed initiatives that would fundamentally alter the operation of the food safety system and the government's role. Currently, the agencies focus their oversight efforts on physical inspections that prevent unsafe food products from leaving food-processing plants. Under the proposed initiatives, industry will be responsible for implementing systems that identify and control potential hazards before food products are affected. The government's oversight role will shift from mainly conducting physical inspections to assessing each plant's safety system and its effectiveness. Such programs are known generically as Hazard Analysis and Critical Control Point (HACCP) systems.

A HACCP system is designed to identify the critical points in food processing and establish controls to prevent adulteration caused by microbiological, chemical, or physical hazards in order to produce safer food products. FDA's and FSIS' HACCP initiatives—which will be mandatory for the meat, poultry, and seafood industries—are expected to be in operation in 1997. To ensure the systems' integrity, the National Academy of Sciences has recommended that plants' HACCP systems be monitored by federal agencies and that the level of monitoring should be based on the compliance history of each plant.² However, because of FDA's resource constraints and FSIS' regulatory restrictions, the agencies are unlikely to inspect plants on the basis of the risk they pose.³ The National Marine Fisheries Service, in the Department of Commerce, has a voluntary HACCP-based inspection program for the fish and seafood industry. Under this program, the National Marine Fisheries Service schedules plant inspections on the basis of risk as determined by previous inspections and the risk associated with the product. A small percentage of seafood processors participate in this program, which is supported by user fees.

²Three National Academy of Sciences' reports discuss HACCP systems: Meat and Poultry Inspection: The Scientific Basis of the Nation's Program (1985), Poultry Inspection: The Basis for a Risk-Assessment Approach (1987), and Seafood Safety (1991).

³Food safety risk has four parts: the risk (1) inherent in the food (e.g., whether it is a high-risk food—like meat, poultry, and seafood—or not); (2) of the type of processing used to create the product (e.g., whether the product is raw, ground, cooked, or frozen); (3) of the plant (e.g., its compliance with sanitation, good manufacturing, and other safety practices); and (4) of the consumer of the food product (e.g., young children or the elderly). This report does not discuss the risk associated with particular consumers.

Background

In 1994, U.S. consumers spent over \$600 billion on food—about \$334 billion for consumption at home and \$268 billion for consumption outside the home. To regulate the safety of this food, the federal government spends over \$1 billion annually, and state governments and industry spend unknown additional amounts. However, foodborne illnesses still occur and are a continuing health and economic concern.

The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services, estimates that over 6 million illnesses and about 9,000 deaths resulting from foodborne pathogens occur each year.⁴ These illnesses and deaths are very costly. For example, FSIS estimated that nearly 5 million illnesses and about 4,000 deaths were caused by meat and poultry products in 1993, at a cost estimated to be from \$4.5 billion to \$7.5 billion.⁵

Twelve federal agencies implement as many as 35 food safety and related laws. The responsibilities of these agencies are outlined in appendix I. FDA, which has primary responsibility for the safety of all foods except meat and poultry,⁶ carries out its responsibility through physical inspections of food-processing plants. FSIS, which has primary responsibility for meat and poultry safety, carries out its responsibility largely through organoleptic inspections of meat and poultry—that is, using sight, smell, and touch—to determine the wholesomeness of products at slaughter plants. These carcass-by-carcass inspections date back to the turn of the century. These continuous inspections at slaughter plants, along with FSIS' daily inspections of processing plants, account for about one-half of the federal government's expenditures for food safety.

In 1992, we reported that this historic approach to food safety is not well suited to preventing the largest current threat to the food safety system—microbiological contamination.⁷ We suggested moving to HACCP systems.

⁴These estimates are based on data from the mid 1980s. Many experts, including CDC officials, believe that these data underestimate the incidence of foodborne illness. However, they are widely cited and considered the best data available.

⁵Proposed rule, Docket No. 93-016P, "Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems," Federal Register (Feb. 3, 1995).

⁶FDA is responsible for the safety of shell eggs, while FSIS is responsible for the safety of processed egg products.

⁷Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

In December 1995, FDA issued a final regulation, effective in December 1997, that requires fish- and seafood-processing plants to establish HACCP systems. FSIS' proposed HACCP regulation for meat and poultry was published in February 1995. The final regulation is expected in early 1996, and FSIS plans for it to become effective in 1997 and be phased in over a period of years. The National Marine Fisheries Service (NMFS) issued its final regulation for its ongoing, voluntary HACCP-based inspection program for fish and seafood products in July 1992. As of February 1996, 88 plants were being inspected under this program. Plants are charged a fee for the inspections.

Federal Food Safety System Is Largely Unchanged Since 1989

The overall structure of and approach taken by the federal food safety system is much the same as it was in 1989. FDA and FSIS are still primarily responsible for regulating food safety. Both agencies continue to physically inspect food-processing plants and products to detect food safety hazards. FDA's inspection frequency continues to be constrained by resources—in 1989, the agency inspected each plant, on average, once every 3 to 5 years. Currently, FDA plans to inspect food-processing plants once every 8 years, on average.⁸ FSIS continues to rely primarily on daily organoleptic inspections to detect contamination in meat and poultry. FSIS' organoleptic methods are not designed to detect microbiological contamination—the most serious threat to human health from meat and poultry.⁹ Both agencies continue to conduct some chemical analyses of products to detect chemical contamination.¹⁰

While the overall structure of and approach taken by the federal food safety system have not changed, FDA and FSIS have both experienced some internal reorganizations in recent years. FDA, for example, reorganized its Center for Food Safety and Applied Nutrition along commodity lines—so there is now the Office of Seafood, for example—rather than by scientific discipline, such as microbiology. Similarly, during its reorganization, USDA transferred all of its food safety activities to FSIS.¹¹ For example, USDA transferred to FSIS responsibility for (1) inspecting egg products from the

⁸FDA has cooperative agreements with state inspection agencies. In 1995, inspections of food-processing plants averaged once every 5 years when both FDA and state resources were used.

⁹Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994).

¹⁰Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

¹¹In accordance with the Department of Agriculture Reorganization Act of 1994, USDA consolidated its food safety responsibilities within FSIS.

Agricultural Marketing Service and for (2) identifying research needs and coordinating efforts among government, industry, and academia on food safety in animal production from the Animal and Plant Health Inspection Service.

In addition to FDA and FSIS, 10 other agencies have limited food safety responsibilities and have had no or limited change in their duties since 1989. Table 1 sets forth the 12 agencies and their responsibilities.

Table 1: Food Safety Responsibilities for 12 Agencies

Agency	Responsibilities	Major initiatives since 1989
Food and Drug Administration (FDA)	Ensure safety of all foods except meat, poultry, and egg products. Also, ensure safety of animal drugs and feeds.	Published final rule that mandates use of HACCP systems for processors of fish and seafood products.
Food Safety and Inspection Service (FSIS)	Ensure safety of meat, poultry, and egg products.	Proposed HACCP inspection for meat and poultry. Gained responsibility for inspecting egg products. Gained responsibility for identifying needs for research on the health of animals when disease also concerns public health.
Animal and Plant Health Inspection Service (APHIS)	Protect animals and plants from disease and pests or when human health may be affected.	Lost responsibility for identifying needs for research on the health of animals when disease also concerns public health.
Grain Inspection, Packers and Stockyard Administration (GIPSA) ^a	Inspect grain, rice, and related products for quality and aflatoxin contamination.	None.
Agricultural Marketing Service (AMS)	Grade quality of egg, dairy, fruit, vegetable, meat, and poultry products.	Lost responsibility for inspecting processed egg products.
Agricultural Research Service (ARS)	Perform food safety research.	None.
National Marine Fisheries Service (NMFS)	Conduct voluntary seafood inspection program.	Implemented voluntary HACCP seafood inspections.
Environmental Protection Agency (EPA)	Establish pesticide tolerance levels.	None.
Centers for Disease Control and Prevention (CDC)	Investigate foodborne disease problems.	None.
Federal Trade Commission (FTC)	Regulate advertising of food products.	None.
U.S. Customs Service (Customs)	Examine/collect food import samples.	None.
Bureau of Alcohol, Tobacco and Firearms (ATF)	Regulate alcoholic beverages.	None.

^aGIPSA replaced USDA's Grain Inspection Service.

While the agencies' structures and approaches to food safety have remained essentially the same over the last 5 years, new congressional

mandates and the growth of the food sector have resulted in increased budgets and greater workloads. For example, in 1990, the Congress enacted food-labeling legislation that requires food companies to provide nutrition information so that consumers can make informed choices. FDA and FSIS were both involved in developing and overseeing these new requirements.¹² In addition, from 1989 through 1994, the food sector grew by about \$89 billion (about \$50 billion in constant dollars), and there has been a large increase in the number of animals slaughtered.

From fiscal year 1989 through fiscal year 1994, the 12 agencies' budgets increased from \$851 million to nearly \$1.2 billion, an increase of about \$170 million when adjusted for inflation. For FDA and FSIS—the two principal food safety agencies—funds for food safety increased by about 37 percent and about 14 percent, respectively, in constant 1989 dollars. The remaining 10 agencies either lost funding or had small increases.

While responsibilities and budgets increased over this period, staffing remained constant at about 17,000 employees.¹³ Table 2 gives information on funding and staffing levels for the 12 agencies for fiscal years 1989 and 1994.

¹²For a discussion of these requirements, see *Nutrition Labeling: FDA and USDA Need a Coordinated Assessment of Food Label Accuracy* (GAO/RCED-95-19, Dec. 29, 1994).

¹³As we noted in the 1990 report, FDA's staffing levels had decreased by about 200 employees from 1980 to 1989. However, from 1980 to 1994, FDA's staffing increased by about 400 employees.

Table 2: Changes in Funding and Staffing Levels for Food Safety at 12 Federal Agencies

Dollars in millions				
Agency	Funding		Staffing	
	Fiscal year 1989	Fiscal year 1994	Fiscal year 1989	Fiscal year 1994
FDA ^a	\$158.30	\$252.20	2,337	2,920
FSIS	457.20	605.60	10,399	10,109
APHIS	0	0	0	0
GIPSA ^b	42.30	44.10	860	685
AMS ^b	97.00	131.00	2,372	2,080
ARS	25.20	37.60	168	134
NMFS ^b	11.60	16.40	265	285
EPA ^c	54.70	93.00	624	785
CDC	2.60	4.00	25	34
FTC	1.99	2.00	29	23
Customs	d	d	d	d
ATF	d	d	d	d
Total	\$850.89	\$1,185.90	17,079	17,055

^aFDA's data include funding and staffing information for the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and field inspection staff. In addition to food safety activities, field inspectors are responsible for activities not directly related to food safety, such as inspecting cosmetics and animal drug firms. FDA officials noted that the 1989 staffing level of 2,337, if calculated the same way that the 1994 level was counted, would have been 2,641.

^bAgency's funding and staffing levels are for both safety and quality inspection activities.

^cWhile a significant portion of EPA's funding and staffing levels for pesticide programs is for food safety activities, these resources also support other activities, for example, evaluating the effects of pesticides on farm workers.

^dThe agency did not provide a detailed analysis of food safety resources.

In the face of increased responsibilities and workloads, FDA and FSIS have reduced the number of food safety inspections and shortened the length of the inspections in each plant, respectively. While FDA has had an increase in its number of inspectors, it performed fewer food safety inspection activities than it did in 1989. Although the number of food-processing plants for which FDA has inspection responsibility remains about the same, at 53,000, other activities for which it has responsibility, such as ones involving blood banks and plants that manufacture medical devices, have higher priority than inspecting food-processing plants. To meet its increased responsibilities, FDA reduced the number of food safety inspections in its operating plan from about once every 3 to 5 years, on average, in 1989 to about once every 8 years in 1994. As a result, the

number of food plants FDA inspected dropped from 6,368 in 1989 to 4,799 in 1994.¹⁴

FSIS' workload also increased because of the growth in the number of animals being slaughtered. Because its staff has not increased sufficiently to carry out carcass-by-carcass and bird-by-bird inspections under its traditional practices, FSIS has taken a number of steps, including having supervisors conduct slaughter inspections, reducing the amount of time spent on inspecting processing plants, and increasing the number of processing plants that inspectors cover. Table 3 shows the increase in the number of animals slaughtered.

Table 3: Number of Animals Slaughtered, Fiscal Years 1989 and 1994

Species	Fiscal year 1989	Fiscal year 1994
Cattle and calves	33,517,563	34,370,227
Hogs	82,110,688	90,206,024
Other meat	5,633,687	5,124,359
Chickens	5,606,057,466	7,188,682,206
Turkeys	243,608,205	277,598,467
Other poultry	25,240,966	25,807,949

New Initiatives Would Fundamentally Alter the Existing Food Safety System

Three federal food safety agencies are embracing HACCP programs, which will fundamentally alter the federal food safety system and industry operations for ensuring meat, poultry, and seafood safety. FDA and FSIS have proposed mandatory HACCP systems for meat, poultry, and seafood. NMFS has adopted a voluntary HACCP-based inspection program for seafood. In contrast to the current system, these initiatives emphasize the detection and prevention of microbiological contamination by the industry and call for the industry's increased accountability for food safety. Federal agencies' inspection roles will also change—in addition to detecting safety hazards, the agencies will oversee the plants' HACCP systems.

Under these HACCP initiatives, industry is responsible for identifying the points where any microbiological, chemical, and physical safety hazard may occur in food production—known as the critical control points—and establishing procedures at those control points to detect and/or prevent such hazards. In addition, plants are required to document their activities, including establishing a record of actions taken to address any safety hazards.

¹⁴For more information on FDA's increased responsibilities and allocation of increased resources, see *Changes in FDA Structure* (GAO/HEHS-96-53R, Dec. 8, 1995).

FDA's and FSIS' current inspection systems concentrate on detecting physical contamination and abnormalities and plants' compliance with good manufacturing practices and sanitation procedures. While each agency performs some testing for microbiological and chemical contamination, these activities are currently a small part of the overall inspection activities. In contrast, HACCP systems call for plants to employ quality control procedures designed to identify opportunities for preventing all safety hazards, including microbiological contamination—the most serious food safety threat. FDA and FSIS plan to continue their inspection activities. In addition, the agencies will oversee the plants' HACCP systems to ensure that each plant implements and operates an effective system.

The scientific community has specified that in order for HACCP systems to be effective, there must be two components: (1) Each plant in the industry must implement an effective HACCP plan, and (2) federal agencies must inspect each plant's HACCP-based quality control system to ensure that it is working as designed. Furthermore, to ensure the systems' integrity, the National Academy of Sciences has recommended that the level of federal inspections be based on the compliance history of each plant and that the risk of the product be based on the safety hazards of each step in production. However, because of FDA's resource constraints and FSIS' regulatory restrictions, the agencies' ability to inspect plants on the basis of the risk they pose is limited.

Specifically, FDA plans to inspect seafood plants once every 2 years, on average, regardless of their compliance history, and plants producing the highest-risk seafood once per year. While individual inspectors may visit noncompliant plants more frequently, other plants will not be inspected as a result because of limited inspection resources. Because FSIS is required by law to have continuous inspections of slaughtering plants and daily inspections of processing plants, the agency must continue its daily and carcass-by-carcass inspections. To take into account food safety risks in processing plants, FSIS plans to consider risk when scheduling the daily tasks that inspectors will perform. In addition, in slaughtering plants, FSIS plans to initiate pilot projects to explore other ways to perform its mandated carcass-by-carcass inspections with fewer resources.

Unlike these other agencies, NMFS bases the frequency of inspections, for seafood plants participating in the voluntary HACCP-based inspection program, on the risk that they present. NMFS determines the riskiness of the plants as indicated by past inspections and the inherent risk associated

with the product. As plants achieve and maintain compliance with NMFS' standards, NMFS reduces the frequency of its inspections. The higher the plant's NMFS rating for safety, the fewer inspections the plant receives and the lower the cost to the plant, since plants pay for the inspection. Plants with the best safety rating are inspected every 6 months, while plants with the lowest safety rating are inspected every 2 weeks. Plants that are not able to maintain compliance with NMFS' program standards are dropped from the program or placed under daily inspection while deficiencies are being corrected. Of the about 300 seafood plants that participate in NMFS' voluntary inspection programs, 88 seafood plants are under the HACCP program. These plants, like the approximately 4,800 total seafood plants, are also subject to FDA's inspections. Appendix II provides a comparison of some aspects of NMFS' and FDA's seafood HACCP initiatives.

Agency Comments

We provided copies of a draft of this report to each of the 12 agencies for its review and comment. Seven of these agencies generally agreed with the information discussed, and provided clarifying comments and technical corrections, which we have incorporated into the report. Four agencies did not have any comments. FDA disagreed with our characterization of HACCP systems as a fundamental change for the agency. FDA officials, including the Strategic Manager for HACCP Policy, viewed the changes planned for the seafood inspection program as a continuation of historical efforts by the agency and cited their low-acid canned food program and their issuance of good manufacturing practices as examples. While we recognize that FDA's approach to food safety has evolved over the years, we continue to believe that the move to HACCP represents a significant shift in FDA's policy. We further believe that our characterization of this shift is consistent with FDA's previous characterizations. In particular, in its HACCP rulemaking proposal, FDA stated that it was responding to the need for a "new paradigm" for seafood inspection, one that provides an ongoing, scientifically established system of intensive, preventative monitoring. We believe that taken in context, the HACCP-related changes being implemented by FSIS, FDA, and NMFS do represent a fundamental shift in the federal government's approach to food safety.

Scope and Methodology

To obtain information on agencies' responsibilities, funding, staffing, and workloads, we asked the 12 agencies involved in food safety to provide data similar to the 1989 data presented in our two-volume 1990 report. We did not verify the accuracy of these data. We also visited five seafood-processing plants that NMFS had identified to understand and

observe how its user-fee, voluntary HACCP-based inspection program worked. In addition, we examined other reports and studies on meat, poultry, and seafood inspection and used prior GAO studies.

We interviewed agency and industry officials and obtained additional data from FDA, FSIS, and NMFS concerning HACCP proposals, plans, and operations. We attended public meetings on FSIS' HACCP proposal. We conducted our work at agencies' headquarters in the Washington, D.C., area and in NMFS' Western Inspection Region. We performed our work from July 1995 through March 1996 in accordance with generally accepted government auditing standards.

We are sending copies of this report to the Senate Committee on Agriculture, Nutrition, and Forestry, and other appropriate congressional committees. We will also send copies of this report to the Secretaries of Agriculture, Commerce, Health and Human Services, and the Treasury; the Administrator, Environmental Protection Agency; and the Commissioner, Federal Trade Commission. We will also make copies available to others upon request.

Please contact me at (202) 512-5138 if you or your staff have any questions. Major contributors to this report are listed in appendix III.

A handwritten signature in black ink, appearing to read "Robert A. Robinson". The signature is fluid and cursive, with a large initial "R" and "A".

Robert A. Robinson
Director, Food and
Agriculture Issues

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Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ATF	Bureau of Alcohol, Tobacco and Firearms
CDC	Centers for Disease Control and Prevention
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GAO	General Accounting Office
GIPSA	Grain Inspection, Packers and Stockyards Administration
HACCP	Hazard Analysis and Critical Control Point
NMFS	National Marine Fisheries Service
USDA	U.S. Department of Agriculture

Responsibilities of Federal Agencies Involved With Food Safety

Food and Drug Administration (FDA) is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act, as amended, is the major law relating to FDA's food safety and quality activities. The act also authorizes FDA to maintain surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe, are properly labeled, and produce no human health hazards when used in food-producing animals.

Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled, and packaged. FSIS carries out its meat and poultry inspection responsibilities under the Federal Meat Inspection Act, as amended, and the Poultry Products Inspection Act, as amended. Amendments to these acts require that meat inspected by state inspection programs and imported meat are to meet inspection standards "at least equal to" those of the federal program. Furthermore, the Department of Agriculture Reorganization Act of 1994 transferred to FSIS food safety inspections previously being performed by other organizations within the U.S. Department of Agriculture (USDA).

Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring the health and care of animals and plants. APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to animal or plant health. APHIS identifies research and data needs and coordinates research programs designed to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety.

Grain Inspection, Packers and Stockyards Administration (GIPSA) is responsible for sharing information with FDA concerning food safety and for ensuring the quality of grains for marketing. For example, GIPSA covers the inspecting of corn, sorghum, and rice for aflatoxin, which causes human illness. GIPSA carries out its responsibilities under the U.S. Grain Standards Act, as amended, and the Agricultural Marketing Act of 1946, as amended.

Agricultural Marketing Service (AMS) is primarily responsible for establishing the standards of quality and condition and for grading the quality of dairy, egg, fruit, meat, poultry, seafood, and vegetable products.

As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS carries out its wide array of programs to facilitate marketing under more than 30 statutes—for example, the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; and the Export Grape and Plum Act, as amended.

Agricultural Research Service (ARS) is responsible for conducting a wide range of research relating to USDA's mission including food safety research. ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.

National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts its voluntary seafood safety and quality inspection programs under the Agricultural Marketing Act of 1946, as amended, and the Fish and Wildlife Act of 1956, as amended. In addition to the inspection and certification services provided for fishery products for human consumption, NMFS also provides inspection and certification services for animal feeds and pet foods containing a fishery base.

Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the country and setting maximum allowed residue levels—tolerances—for pesticides on food commodities and animal feed. EPA's activities are conducted under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug, and Cosmetic Act, as amended.

Centers for Disease Control and Prevention (CDC) is charged with protecting the nation's public health by providing leadership and direction in preventing and controlling diseases and responding to public health emergencies. CDC engages in public health activities related to food safety under the general authority of the Public Health Service Act, as amended.

Federal Trade Commission (FTC) enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC's food safety objective is to prevent consumer deception through the misrepresentation of food.

Appendix I
Responsibilities of Federal Agencies
Involved With Food Safety

U.S. Customs Service (Customs) is responsible for collecting revenues and enforcing various customs and related laws. Customs assists FDA and FSIS in carrying out their regulatory role in food safety.

Bureau of Alcohol, Tobacco and Firearms (ATF) is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.

Comparison of NMFS' and FDA'S Seafood HACCP Initiatives

Subject	NMFS	FDA
Key definition	<p>Critical control point: Any step in a process that, if not properly controlled, may result in an unacceptable safety, wholesomeness, or economic fraud risk.</p> <p>Process: One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.</p>	<p>Critical control point: A point in a food process at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.</p> <p>Processing: With respect to fish or fishery products, the handling, storing, preparing into different market forms, packing, labeling, or holding of a product.</p>
HACCP plan's requirement	<p>Firms that wish to participate in the program may apply orally or in writing. However, the applicant must submit a written HACCP plan, which must be reviewed and approved prior to validation.</p>	<p>Every processor shall conduct a hazard analysis to determine whether food safety hazards are reasonably likely to occur and to identify preventive measures. If this analysis reveals one or more such hazards, the processor shall implement a written HACCP plan for each processing location and for each kind of fish and fishery product.</p> <p>Failure to have and implement a HACCP plan that complies with the requirements shall render the products adulterated.</p>
HACCP plan's content requirements	<p>(1) Organization chart and narrative describing duties of personnel. (2) Description of fishery products. (3) Process flow charts. (4) Critical control point work sheet, including critical points, hazards, preventive measures, critical limits, monitoring procedures, corrective actions, and records. (5) Record-keeping system. (6) Verification procedures. (7) Sanitation standard operating procedures. (8) Consumer complaint file. (9) Recall procedures.</p>	<p>(1) A list of the food safety hazards that are reasonably likely to occur and thus must be controlled for each fish and fishery product. (2) A list of the critical control points for each identified hazard. (3) List of the critical limits that must be met at each of the critical control points. (4) Procedures used to monitor each of the critical control points to ensure compliance with critical limits. (5) Any corrective action plans that have been developed to respond to deviations from critical control point limits. (6) List of the verification procedures and frequency of verification. (7) Record-keeping system to document monitoring of critical control points.</p>
HACCP plan's review and approval	<p>On a fee basis, regional officials will review and approve a HACCP plan. When ready for validation, the plan is sent to the National HACCP Coordinator for final review and approval. One or more Consumer Safety Officers and inspectors will perform an on-site validation of the plan. The validation team will conduct the test after the firm has operated for at least 10 production days.</p>	<p>FDA's HACCP rule does not mention any requirement for prior FDA review and approval of a firm's HACCP plan.</p> <p>FDA's HACCP rule provides for an overall verification that the HACCP plan is being effectively implemented.</p>

(continued)

Appendix II
Comparison of NMFS' and FDA'S Seafood
HACCP Initiatives

Subject	NMFS	FDA
Training	Each facility must employ a NMFS-certified person knowledgeable of the HACCP program's principles to be present during all processing times.	Functions, such as developing a HACCP plan, reassessing and modifying the HACCP plan, and performing the record review, shall be performed by an individual who has successfully completed a standardized course of instruction recognized by FDA in the application of HACCP principles in the processing of fish and fishery products at a program of instruction approved by FDA. This trained individual need not be an employee of the processor.
Systems audits	Different audit schedules exist for participating vessels, processors, and retail and food service firms. The audit schedules are on a sliding frequency scale: as performance improves, the frequency of audits decreases. Audits are unannounced. For processors, the frequency ranges from daily audits in plants that are temporarily out of compliance to audits every 6 months for a high level of proven compliance. The entry level in the HACCP program calls for audits every 2 weeks.	FDA plans to review the seafood-processing plants about once every 2 years on average. These inspections have occurred nearly once per year, on average, for the highest-risk fish and seafood firms and about once every 3 to 4 years, on average, for low-risk firms.
Records retention	All of the plant's records must be maintained by the firm for a period of 6 months beyond the expected shelf life of the product and must be accessible at all times to NMFS' inspection personnel.	Records required by the regulations shall be retained at the processing facility or importer's business for at least 1 year after preparation for refrigerated products and 2 years for frozen, shelf-stable, or processed products. All records shall be available for official review and copying by FDA inspectors.
Fees	NMFS has fees and charges to recover costs for administering the HACCP program. Fees are collected for preplan consultation, plan review and validation, inspections, and laboratory analysis of samples. Travel and per diem charges are added.	FDA will not fund the additional work on HACCP's compliance with user fees.

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